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COUNCIL OF EUROPE

The Recommendation on Research on Biological Materials of Human Origin: Another Brick in the Wall

Introduction

Given the goals, direction and growing capabilities of modern biomedical research, human biological material, in addition to being of great value,¹ is of great significance to improving human health and healthcare. It is also a potential site for violations of our human rights. Recognising this early on, the Council of Europe adopted the Biomedicine Convention (1997),² which was one of the first international instruments to recognise the scientific, therapeutic and commercial value of human tissue, and link research utilising it to human rights.³ It then adopted the Additional Protocol (2005),⁴ which addressed human subject research more specifically. On 15 March 2006, it took further action at the human tissue/human rights nexus by adopting a draft Recommendation on Research on Biological Materials of Human Origin,⁵ an instrument concerned not with traditional human subject research, but with the procurement, storage and utilisation of excised human tissue for research.

The Committee of Ministers of the Council of Europe justified its introduction of yet another (non-binding) international instrument in this field on the grounds that worries over data security and scandals concerning unauthorised use of tissue

1 The human tissue market was calculated at over US\$4 billion in 2001: M. Reymond et al., "Ethical, Legal and Economic Issues Raised by the Use of Human Tissue in Post-genomic Research" (2002) 20 *Dig. Dis.* 257-265.

2 Convention for the Protection of Human Rights and Dignity of Human Beings with regard to the Applications of Biology and Medicine, ETS No. 164, 1997.

3 See Articles 11, 12, 16, 17, 21 and 22 of the Biomedicine Convention, and its associated Explanatory Report, all discussed in S. Gevers, "Human Tissue Research With Particular Reference to DNA Banking" in J. Gevers et al. (eds), *Health Law, Human Rights and the Biomedicine Convention* (Leiden: Martinus Nijhoff, 2005) 231-243.

4 Additional Protocol to the Biomedicine Convention, ETS No. 195, 2005.

5 Rec(2006)4, March 15, 2006, 958th meeting of the Ministers' Deputies.

persist, and there is no international regulation to cover this particular type of research.⁶ Unfortunately, even a cursory review of the Recommendation exposes the fact that it contains little in the way of original contribution to biomedical research regulation; it reiterates well worn general principles, albeit in the context of biobanks (and population biobanks).⁷ However, the excised human tissue storage/research context throws up unique regulatory issues and opportunities, making the Council's status quo approach is somewhat disappointing. A few observations should serve to illustrate the narrowness of its approach. Thus, after first briefly review the Recommendation's philosophical foundation and substantive content, I will address some key issues of particular relevance to biobanks, namely (1) consent, (2) commercialisation, (3) custodianship, and (4) collapse.

Analysis

I. Perspective and provisions of the recommendation

That the human rights perspective (founded on the values of autonomy and equality) informed the Council's effort, and that the Recommendation is intended to be a human rights protecting instrument is obvious from the Explanatory Memorandum:

... If [human biological material] were not utilised and research had to be undertaken relying only on prospective collection of biological materials specifically for each project, it would mean ... comparable research results would not be available for ... years. ... The purpose of this recommendation is to set out and safeguard fundamental rights of individuals whose biological materials are used in biomedical research, while recognising the importance of freedom of research.⁸

6 Steering Committee on Bioethics, Explanatory Memorandum, CDBI (2005) 5REV2, at 1-2.

7 Indeed, as conceded in the Preamble and the Explanatory Memorandum, much of the content is already enunciated in other international instruments. In particular, see the European Convention on Human Rights (1950), the European Convention on Personal Data (1981), and the Biomedicine Convention (1997) and its Additional Protocol Concerning Biomedical Research (2005), the UNESCO International Declaration on Human Genetic Data (2003), as well as the more binding EU Personal Data Directive 95/46/EC, and the EU Good Clinical Practice Directive 05/28/EC. The proliferation of regulation, particularly that addressing use of genetic data, which is assumed to be special, is also noted by J. Bovenberg, *Property Rights in Blood, Genes and Data: Naturally Yours?* (Leiden: Martinus Nijhoff, 2006), at 8-28.

8 Steering Committee on Bioethics, *supra*, note 6, at 2-3.

It is equally obvious from the first provisions of the Recommendation itself, which commences by enunciating some general principles applicable to the full range human tissue research and human tissue banking. In particular, the Preamble states that:

- the interests and welfare of tissue donors shall prevail over others' interests;
- appropriate and transparent governance of stored human tissue is important;
- people must be freed to accept or refuse to contribute to biomedical research;
- a paramount concern should be protection of the human being; and
- measures must be taken to safeguard human dignity and individual rights.

Article 1 then directs member states to protect the dignity, identity, private life, integrity, and other fundamental freedoms, without discrimination, of all human beings with regard to research.⁹

Article 2 articulates the scope of the Recommendation, stating that it applies to "biological material of human origin". It specifies that this phrase does not include embryonic or foetal tissue,¹⁰ but does include associated personal data (eg: data derived from biological samples).¹¹ Unfortunately, it does not go on to define this phrase with any greater particularity; it could include cadavers, organs, tissues (biopsy and surgical specimens), cells (from organs, umbilical cord, bone marrow or gonadic), body fluids (blood, semen, saliva), hair, nails and body waste products (urine, faeces).¹² Article 3 defines "identifiable biological materials" as "identified", "coded" or "linked anonymised", and "non-identifiable biological materials" as "unlinked anonymised".¹³ Article 8 states that tissue and data should be "anonymised as far as appropriate to the research concerned", and that any use of "identified", "coded" or "linked anonymised" tissue/data should be justified.

Reflecting the autonomy/equality based human rights foundation of the Recommendation, Articles 5 and 6 state that risks to participants and their families, particularly regarding private life and discrimination, should be "minimised", and risks should not be disproportionate to the potential benefit of the research. Article 7 states that biological materials should not, as such, give rise to financial gain.

⁹ This represents a continuation of the principles advanced in the Biomedicine Convention (1997), which are discussed in J. Dute, "The Leading Principles of the Convention on Human Rights and Biomedicine" in J. Gevers *et al.* (eds), *supra*, note 3, 3-12.

¹⁰ Article 2, Clause 3.

¹¹ Article 2, Clause 4, and Article 3.

¹² M. Reymond *et al.*, *supra*, note 1, at 259.

¹³ For a comment on the confusion of terminology used in this particular research area, see B. Elger & A. Caplan, "Consent and Anonymization in Research Involving Biobanks" (2006) 7 *EMBO Reports* 661-666.

This is an oft flogged provision intended to keep tissue originators from receiving financial rewards in exchange for their tissue, and is widely (though certainly not universally) deemed necessary to protect human dignity and avoid undue influence and instrumentalisation of the person. Article 9 stipulates that the Recommendation does not limit the ability of member states to grant wider protections.

The remainder of the Recommendation addresses more specifically the mechanics of procuring human tissue (with an unsurprising emphasis on consent), collecting human tissue in biobanks, and subsequent use of human tissue in research projects. These matters are considered in greater detail below within the context of the four issues of particular concern to biobank operations.

II. The recommendation's management of the four "Cs"

Consent

The Recommendation deals with individual consent at some length. As a preliminary matter, it states that, whether seeking tissue from adults, minors or cadavers, the information provided to the person authorised to give consent, and the consent obtained should be as specific as possible with regard to any foreseen research.¹⁴ Further, whenever possible, consent should be obtained before tissue is removed.¹⁵ Research undertaken on the tissue should fall within the scope of the consent given, even where the tissue is unlinked anonymised.¹⁶ Where a research project falls outside the consent, "reasonable efforts" should be made to re-contact the person and obtain consent.¹⁷ If this is not possible, the tissue/data can be used subject to an "independent evaluation" (by an independent ethics review board?) concluding that the project fulfils certain conditions, namely that:¹⁸

- a) the research addresses an important scientific interest;
- b) the research's aims could not reasonably be achieved using tissue for which consent can be obtained; and
- c) there is no evidence that the person expressly opposed such research.

¹⁴ Article 10.

¹⁵ Article 12.

¹⁶ Articles 21 and 23.

¹⁷ Article 22, Clause 1.i.

¹⁸ Article 22, Clause 1.ii.

These criteria throw up some obvious questions with which national legislators or the independent review body will have to grapple: Is the scientific interest ever not important and from whose perspective is that determination made? What is the balance of convenience surrounding re-contact? How would the collection custodian know what a participant opposes; would it be contained on the consent form?

Interestingly, the Recommendation also states that consent can contain restrictions on the use of the tissue/data, and it can be altered or withdrawn at any time, and such must not lead to discrimination against the participant.¹⁹ In the event of withdrawal, the tissue must be destroyed or rendered “unlinked anonymised”.²⁰ This means that the tissue, alone or in combination with associated data, does not allow, with “reasonable efforts”, the identification of the persons concerned.²¹ The Recommendation gives no indication as to what might constitute “reasonable efforts”. The practical implications of this position would seem to be:

- increased complexity of consent forms;
- increased administrative duties related to policing a system of different categories/classes of participants and potentially shifting participants from one category to another;
- increased expenses and potentially prohibitive budgetary demands; and
- increased likelihood of negative knock-on effects for specific research projects.

Consent is never easy to get right, and it is manifestly more difficult in the biobank context, which is unique in that biobanks are:²²

- collective (relying on mass participation);
- inclusive (recruiting healthy people and most effective with children recruits);
- prospective (ideally enduring beyond the life of original participants); and
- purposively indeterminate (impossible for clinicians, custodians, or current researchers to inform participants of future research ends and therefore of potential risks and benefits).

This reality sits uneasily with our over-emphasis on specific and individual consent and its use as the panacea for promoting human dignity. Even the few observations made above demonstrate this uneasiness, and suggest that the multiple provisions

¹⁹ Article 15, Clauses 1, 2 and 3, and Article 22, Clause 2.

²⁰ Article 15, Clause 1.

²¹ Article 3, Clause ii.

²² For more on their nature, see G. Williams, “Bioethics and Large-Scale Biobanking: individualistic Ethics and Collective Projects” (2005) 1 *G.S.P.* 50-66.

addressing consent in the Recommendation are sure to prompt interesting responses, particularly from custodians of existing biobanks which do not offer participants such a range of options.

Parenthetically, as an alternative to consent but without having to abandon all of the mechanisms erected, it seems more appropriate in the biobank context for the custodian to obtain the “agreement” of the subject to participate in the biobank (eg: donate tissue and information), and “permission” for the excised tissue to participate in future unknown research within reasonably articulated parameters. This may be semantic, but it has the benefit of not stretching our understanding of valid informed consent out of all proportion for the purpose of pursuing biobanks. In addition, assuming the custodian obtains agreement and permission, and drawing on solidarity,²³ one might question the value of permitting participants to withdraw from biobanks completely.²⁴

Commercialisation

The Recommendation employs the rhetoric of solidarity as the basis for tissue donation.²⁵ It then reiterates the standard admonition that biological material should not, *as such*, give rise to financial gain.²⁶ However, it is deafeningly silent on all other aspects commercialisation and financial gain.

For example, it offers no guidance concerning the economics of running a biobank (ie: allowable fees for making the resource available to private researchers), and, more significantly, it is mute as to the duties of the profit-seeking private research entities who are expected to use collections. Aside from a bland statement against discrimination and stigmatisation, there is nothing about their duty to conduct and

23 For more on solidarity, see S. Harmon, “Regulation of Human Genomics and Genetic Biotechnology: Risk, Values and Analytical Criteria” (2005) *INNOGEN Working Paper* 40, at www.innogen.ac.uk/assets_innogen/dynamic/1132844739842/Innogen-Working-Paper-40.pdf, S. Harmon, “From Engagement to Re-Engagement: The Expression of Moral Values in European Patent Proceedings, Present and Future” (2006) 31 *E.L.Rev.* 642-666, and S. Harmon, “Solidarity: A (New) Ethic for Global Health Policy” (2006), forthcoming in *Health Care Analysis*.

24 I recognise that a right of withdrawal is usually extended as a means of promoting trust (see UK Biobank and Generation Scotland), but one can argue that the right really has very little bearing on promoting trust as it will only ever be exercised when there is a loss of trust for whatever reason. In any event, there are more effective ways to promote/ensure trust: see *infra*.

25 Preamble.

26 Article 7.

to avoid certain types of research, or to contribute to basic knowledge and public health through biobank-facilitated research.

This is a troubling lacunae for at least two reasons. First, biobank usage is now and is expected in future to be driven largely by economic interests.²⁷ Second, it should by now be clear to regulators that publics have concerns around the role and conduct of profit-seeking entities in human subject research and public health-care agenda-setting.²⁸ Some guidance around biobank user duties would go far in promoting trust in tissue originators and the public of biobanks, biobank custodians and biobank utilisers; trust being an essential component of the success of biobanks and medical research more generally.²⁹ I would suggest that such guidance would go farther than the “right to withdraw” in promoting this trust. Additionally, if the Council of Europe was truly interested in advancing solidarity and more effectively promoting trust, it would have articulated some concrete duty to benefit share whenever this resource was used, and offered some specific guidance or principles or model example with respect to benefit sharing.

Custodianship

The Recommendation states that “appropriate and transparent” governance of human tissue is essential,³⁰ and it goes on to give some content to this claim by suggesting that governance structures and instruments should:

- state the purposes of the collection;³¹
- address access, use and transfer of tissue and data clearly and transparently;³²
- erect clear security and confidentiality protocols relating to tissue and data;³³
- allow for independent ethical oversight of proposed projects;³⁴
- conduct regular audits on implementation of procedures;³⁵

27 See G. Williams, *supra*, note 22, and others.

28 See S. Wilkinson, “Biomedical Research and the Commercial Exploitation of Human Tissue” (2005) 1 *G.S.P.* 27-40.

29 See G. Haddow, G. Laurie, S. Cunningham-Burley & K. Hunter, “Tackling Community Concerns About Commercialisation of Genetic Research: A Modest Interdisciplinary Proposal”, forthcoming in *Social Science and Medicine*.

30 Preamble.

31 Article 14, Clause 2.

32 Article 14, Clauses 2 and 4.

33 Article 14, Clause 5.

34 Articles 18 and 19, Clause 1.

35 Article 19, Clause 2.

- require activity reports;³⁶ and
- only permit the cross-border transfer of tissue/data where evidence of adequate protection exists.³⁷

These conditions, and compliance with transparency and accountability as the governing principles of biobank management, are all very useful and sensible, but I would suggest that they are not enough.

The Recommendation offers no suggestion as to what constitutes an appropriate consequence for serious breach of these provisions. Without sanctions, all of these very useful “rules” may amount to very little. Further, it pays little attention to the duties of biobank custodians to realise a significant contribution to “saving lives and improving their quality”, a widely claimed aim for biobanks.³⁸ For example, there is nothing directing custodians to proactively steer the usage of the biobank toward broadly beneficial projects that will enhance (public) healthcare and thereby maximise their contribution to worthy, publicly endorsed ends.³⁹ Usage is left in the hands of the (largely private, profit-seeking) entities who choose to submit research proposals to the custodian. At least there is some ethical oversight envisioned, but this does little to ensure that public (and international), as opposed to purely commercial, ends are pursued.⁴⁰

Collapse

A perceived strength of biobanks is their promise of durability and growth (which fuels anticipation that future projects will be increasingly benefited). However, experience has already demonstrated that biobanks can fail.⁴¹ What is the appropriate regulatory response to failure of a biobank? The Recommendation does not address this, saying only that “procedures should be developed for the ... closure of a population biobank”.⁴² An instrument directed at human tissue use and banking, with their unique possibility of unanticipated collapse, should surely be

³⁶ Article 19, Clause 4.

³⁷ Article 16.

³⁸ And one contained in the Preamble to the Recommendation.

³⁹ G. Williams & D. Schroeder, “Human Genetic Banking: Altruism, Benefit and Consent” (2004) 23 *New. Gen & Soc.* 89-103, at 97.

⁴⁰ For more on the need of a broader (global) view and a solidarity-based approach in human subject research, see S Harmon, “Solidarity: A (New) Ethic for Global Health Policy” (2006), forthcoming in *Health Care Analysis*.

⁴¹ Note the Icelandic and the Estonian examples.

⁴² Article 19, Clause 3.

expected to address this issue more squarely by articulating some baseline principled rules with respect to winding down (and the transfer or destruction of the tissue which made the resource so valuable in the first place).

Conclusion

Given the obvious and direct applicability of other instruments to this field, one wonders about the potential impact of the Recommendation. However, having decided to act, the Council of Europe should have taken more direct notice of the *sui generis* nature of biobanks and their special possibilities and pitfalls, which places their regulation in a unique position to draw on and provide a strong vehicle for the realisation of important values like solidarity. I understand that the Recommendation is an international instrument intended for uptake by differing political/legal cultures, and, as such, it is possible that the drafters attempted to keep it reasonably open (non-specific). Indeed, they may question the wisdom of offering examples, models and suggested sanctions (as has been suggested above). However, because this is an international instrument which is really only intended to serve as a model for regulation, I suggest that offering examples and models is indubitably appropriate. More specific and binding domestic laws will likely only be loosely based on it (if at all) and will likely cherry pick from the provisions deemed most appropriate. Offering the most comprehensive example of regulation might make the Recommendation more useful to drafters. As it is, what we (and member states) are left with is another brick in the rising wall of vague, autonomy-promoting, unenforceable instruments.

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COUNCIL OF EUROPE COMMITTEE OF MINISTERS

Recommendation Rec(2006)4 of the Committee of Ministers to member states on research on biological materials of human origin

*(Adopted by the Committee of Ministers on 15 March 2006
at the 958th meeting of the Ministers' Deputies)*

Preamble

The Committee of Ministers, under the terms of Article 15.b of the Statute of the Council of Europe,

Considering that the aim of the Council of Europe is the achievement of greater unity between its members and that one of the methods by which this aim is pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Considering that one of the aims of the Convention for the Protection of Human Rights and Fundamental Freedoms (ETS No. 5) is the protection of private life;

Considering that the aim of the Convention on Human Rights and Biomedicine (ETS No. 164, hereinafter referred to as "the Convention") and of its Additional Protocol concerning biomedical research (CETS No. 195), as defined in Article 1 of both instruments, is to protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine;

Considering that progress in medical and biological sciences, in particular advances obtained through biomedical research, including research using biological materials donated in a spirit of solidarity, contributes to saving lives and improving their quality;

Conscious of the fact that the advancement of biomedical science and practice is dependent on knowledge and discovery which necessitates research on human beings and research involving the use of biological materials of human origin;

Stressing that such research is often transdisciplinary and international;

Taking into account the current and planned development of collections and banks of biological materials at national level;

Taking into account national and international professional standards in the area of biomedical research and the previous work of the Committee of Ministers and the Parliamentary Assembly of the Council of Europe in this field;

Convinced that biomedical research that is contrary to human dignity and human rights should never be carried out;

Stressing that the paramount concern should be the protection of the human being whose biological materials are removed, stored or used for research;

Recalling that research on biological materials should be carried out freely subject to the provisions of this recommendation and the other legal provisions ensuring the protection of the human being;

Emphasising that the interests and welfare of the human being whose biological materials are used in research shall prevail over the sole interest of society or science;

Affirming that particular protection shall be given to human beings who may be vulnerable in the context of research;

Recognising that every person has the right to accept or refuse to contribute to biomedical research and that no one should be forced to contribute to it;

Stressing the importance of appropriate and transparent governance of biological materials stored for research purposes;

Stressing that population biobanks developed on the basis of donations of biological materials made in a spirit of solidarity should not be monopolised by small groups of researchers;

Resolving to take such measures as are necessary to safeguard human dignity and the rights and fundamental freedoms of the individual with regard to biomedical research on biological materials of human origin,

Recommends that the governments of member states adapt their laws and practices to the guidelines contained in appendix to this recommendation and promote the establishment of practice guidelines to ensure compliance with the provisions contained in this appendix;

Entrust the Secretary General of the Council of Europe to transmit this recommendation to the governments of the non-member states of the Council of Europe which have been invited to sign the Convention on Human Rights and Biomedicine, to the European Community and to the international organisations participating in the work of the Council of Europe in the fields of bioethics.

* * *

*Appendix to Recommendation Rec(2006)4***Guidelines****CHAPTER I****Object, scope and definitions****Article 1 – Object**

Member states should protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity, right to private life and other rights and fundamental freedoms with regard to any research governed by this recommendation.

Article 2 – Scope

1. This recommendation applies to the full range of research activities in the health field involving the removal of biological materials of human origin to be stored for research use.
2. It also applies to the full range of research activities in the health field involving the use of biological materials of human origin that were removed for a purpose other than that mentioned in the previous paragraph; this includes material removed for a previous research project.
3. This recommendation does not apply to embryonic and foetal tissues.
4. The use of biological material of human origin may be accompanied by the use of associated personal data.

Article 3 – Identifiability of biological materials

Biological materials referred to in Article 2 may be identifiable or non-identifiable:

- i. *Identifiable biological materials* are those biological materials which, alone or in combination with associated data, allow the identification of the persons concerned either directly or through the use of a code.

In the latter case, the user of the biological materials may either:

- a. have access to the code: the materials are hereafter referred to as “coded materials”;
or
- b. not have access to the code, which is under the control of a third party: the material are hereafter referred to as “linked anonymised materials”.

- ii. *Non-identifiable biological materials*, hereafter referred to as “unlinked anonymised materials”, are those biological materials which, alone or in combination with associated data, do not allow, with reasonable efforts, the identification of the persons concerned.

CHAPTER II

General provisions

Article 4 – Codes of good practice

Member states should promote the establishment of codes of good practice to ensure compliance with the provisions of this recommendation.

Article 5 – Risks and benefits

1. The risks for the persons concerned and, where appropriate, for their family, related to research activities, in particular the risks to private life, should be minimised, taking into account the nature of the research activity. Furthermore, those risks should not be disproportionate to the potential benefit of the research activities.
2. Possible risks for the individuals in the same group as the person concerned should also be taken into consideration in this context.

Article 6 – Non-discrimination

Appropriate measures should be taken, in the full range of research activities, to avoid discrimination against, or stigmatisation of, a person, family or group.

Article 7 – Prohibition of financial gain

Biological materials should not, as such, give rise to financial gain.

Article 8 – Justification of identifiability

1. Biological materials and associated data should be anonymised as far as appropriate to the research activities concerned.
2. Any use of biological materials and associated data in an identified, coded, or linked anonymised form should be justified by the researcher.

Article 9 – Wider protection

None of the provisions of this recommendation should be interpreted as limiting or otherwise affecting the possibility for a member state to grant a wider measure of protection than is stipulated in this recommendation.

CHAPTER III**Obtaining biological materials for research****Article 10 – Obtaining biological materials for research**

1. Biological materials should be obtained for research in accordance with the provisions of this chapter.
2. Information and consent or authorisation to obtain such materials should be as specific as possible with regard to any foreseen research uses and the choices available in that respect.

Article 11 – Interventions on a person

An intervention should only be carried out to obtain biological materials for storage for research purposes if it complies with the Additional Protocol concerning biomedical research (CETS No. 195, 2005).

Article 12 – Residual biological materials

1. Biological materials removed for purposes other than storage for research should only be made available for research activities with appropriate consent or authorisation, or in accordance with the provisions of Article 22 paragraph 1.ii.
2. Whenever possible, information should be given and consent or authorisation requested before biological materials are removed.

Article 13 – Biological materials removed after death

1. Biological materials should not be removed from the body of a deceased person for research activities without appropriate consent or authorisation.
2. Biological materials should not be removed or supplied for research activities if the deceased person is known to have objected to it.

CHAPTER IV**Collections of biological materials****Article 14 – Principles applicable to all collections of biological materials**

1. The person and/or institution responsible for the collection should be designated.

2. The purpose(s) of a collection should be specified. The principles of transparency and accountability should govern its management, including access to and use and transfer of its biological materials and disclosure of information.
3. Each sample of biological material in the collection should be appropriately documented, including information on any relevant consent or authorisation.
4. Clear conditions governing access to, and use of, the samples should be established.
5. Quality assurance measures should be in place, including conditions to ensure security and confidentiality during storage and handling of the biological materials.

Article 15 – Right to change the scope of, or to withdraw, consent or authorisation

1. When a person has provided consent to storage of identifiable biological materials for research purposes, the person should retain the right to withdraw or alter the scope of that consent. The withdrawal or alteration of consent should not lead to any form of discrimination against the person concerned, in particular regarding the right to medical care.

When identifiable biological materials are stored for research purposes only, the person who has withdrawn consent should have the right to have, in the manner foreseen by national law, the materials either destroyed or rendered unlinked anonymised.

2. Where authorisation has been given on behalf of a person not able to consent, the representative, authority, person or body provided for by law should have the rights referred to in paragraph 1 above.
3. Where a person on whose behalf authorisation has been given attains the capacity to give consent, that person should have the rights referred to in paragraph 1 above.

Article 16 – Transborder flows

Biological materials and associated personal data should only be transferred to another state if that state ensures an adequate level of protection.

CHAPTER V

Population biobanks

Article 17 – Scope of chapter V

1. A population biobank is a collection of biological materials that has the following characteristics:
 - i. the collection has a population basis;

- ii. it is established, or has been converted, to supply biological materials or data derived therefrom for multiple future research projects;
- iii. it contains biological materials and associated personal data, which may include or be linked to genealogical, medical and lifestyle data and which may be regularly updated;
- iv. it receives and supplies materials in an organised manner.

2. Population biobanks should meet the requirements set out in this chapter in addition to those of chapter IV.

3. Member states should consider applying the provisions of this chapter to collections that have some, but not all, of the characteristics specified in paragraph 1.

Article 18 – Independent examination

A proposal to establish, or to convert a collection to, a population biobank should be subject to an independent examination of its compliance with the provisions of this recommendation.

Article 19 – Oversight of population biobanks

- 1. Each population biobank should be subject to independent oversight, in particular to safeguard the interests and rights of the persons concerned in the context of the activities of the biobank.
- 2. Regular audits should be conducted of the implementation of procedures on access to, and use of, samples.
- 3. Procedures should be developed for the transfer and for the closure of a population biobank.
- 4. Population biobanks should publish reports on their past and planned activities at least annually, or more frequently if appropriate.

Article 20 – Access to population biobanks

- 1. Member states should take appropriate measures to facilitate access by researchers to biological materials and associated data stored in population biobanks.
- 2. Such access should be subject to the conditions laid down in this recommendation; it may also be subject to other appropriate conditions.

CHAPTER VI**Use of biological materials in research projects****Article 21 – General rule**

Research on biological materials should only be undertaken if it is within the scope of the consent given by the person concerned. The person concerned may place restrictions on the use of his or her biological materials.

Article 22 – Identifiable biological materials

1.i. If the proposed use of identifiable biological materials in a research project is not within the scope of prior consent, if any, given by the person concerned, reasonable efforts should be made to contact the person in order to obtain consent to the proposed use.

ii. If contacting the person concerned is not possible with reasonable efforts, these biological materials should only be used in the research project subject to independent evaluation of the fulfilment of the following conditions:

- a. the research addresses an important scientific interest;
- b. the aims of the research could not reasonably be achieved using biological materials for which consent can be obtained; and
- c. there is no evidence that the person concerned has expressly opposed such research use.

2. The person concerned may freely refuse consent for the use in a research project of his or her identifiable biological materials, or withdraw consent, at any time. Refusal to give consent or the withdrawal of consent should not lead to any form of discrimination against the person concerned, in particular regarding the right to medical care.

Article 23 – Unlinked anonymised biological materials

1. Unlinked anonymised biological materials may be used in research provided that such use does not violate any restrictions placed by the person concerned prior to the anonymisation of the materials.

2. Anonymisation should be verified by an appropriate review procedure.

Article 24 – Independent review

1. Research should only be undertaken if the research project has been subject to an independent examination of its scientific merit, including assessment of the importance of the aim of the research, and verification of its ethical acceptability. National law may additionally require approval by a competent body.

2. Member states should apply the provisions concerning ethics committees contained in chapter III of the Additional Protocol concerning biomedical research (CETS No. 195, 2005) to the review of research within the scope of this recommendation.

3. Review procedures may be adapted to the nature of the research and the extent to which the persons concerned could be identified from their biological materials or associated data.

Article 25 – Confidentiality and right to information

The principles of chapter VIII (confidentiality and right to information) of the Additional Protocol concerning biomedical research should be applied to any research project using biological materials and associated personal data.

CHAPTER VII

Re-examination of the recommendation

Article 26 – Re-examination of the recommendation

This recommendation should be re-examined not more than five years after its adoption, notably in the light of the experience acquired in the implementation of its guidelines.